1. Introduction/Background/General, etc.

1.1 Overview

This LIG provides guidance for the developing and implementation of Issues Management process meeting the requirements of LIR 307-01-05, "Issues Management Program."

1.2. Document Hierarchy

- 10 CFR 830 Subpart A, "Quality Assurance Requirements"
- DOE O 414.1**A, "**Quality Assurance"
- Performance Assurance, LANL, LPR307-01-00
- Issues Management Program, LANL, LIR 307-01-05.0

1.3 Table of Contents

2. Purpose

This procedure provides guidance for the implementation of the LANL Issues Management Program described in LIR 307-01-05.0. The LIG provides guidance for the identification of issues, categorizing issues for significance, entering and updating identified issues into the tool for issues tracking (Institutional tracking system), and performing causal analysis including root cause analysis (RCA) and apparent cause analysis (ACA). It also provides guidance for the development of corrective actions and a corrective action plan (CAP) to correct and prevent recurrence of identified performance issues, guidance for performing end point assessments to evaluate the effectiveness of corrective actions, and guidance for monitoring performance through trend analysis.

3. Scope/Applicability

This procedure should be considered by all Laboratory organizations and personnel implementing LIR 307-01-05.0, *Issues Management*.

4. Definitions

Action to prevent recurrence (ATPR). Actions generally intended to be in place for the long-term and designed to preclude recurrence of the issue. ATPRs address the identified root cause, will prevent recurrence, and will not create another undesirable condition. ATPRs should be a cost-effective alternative and be within the capability of management to implement in a reasonable timeframe. ATPRs should consider first elimination of the hazard, or substitution of the energy source with a less hazardous energy source; engineered and administrative barriers, and performance surety barriers.

Adverse trend. A series of issues in which the frequency combined with the significance of the issue warrants further evaluation and/or corrective action.

Apparent cause. The most likely cause of the failure, given the way the failure manifests itself. This is often determined by looking at the human behavior or the organizational and programmatic issues that triggered the event and consequence.

Apparent cause analysis. A causal analysis that identifies the most obvious direct causes (usually human error, inappropriate action, or equipment failure) and root causes without the rigor of a formal investigation and causal analysis process.

Barrier. Anything that is used to protect something of value (personnel, equipment, or organizational good will) from an energy source (hazard or problem). Barriers may be physical (doors, safety flagging, locked valve) or administrative (procedures, forms, meetings). Barriers also prevent indirect hazards from affecting individuals (supervisor, training, etc.).

Causal factor. A factor that shaped the outcome of an event or condition, made it worse, made it happen sooner, or prevented detection or intervention.

Common cause. A direct, root, or contributing cause that plays a role in multiple events within a period of interest.

Combining issues. Similar identified issues that are tracked in the institutional tracking system, and corrected in aggregate instead of separately.

Conclusion. The resulting consequence of facts.

Contributing cause. A cause that, if corrected would not by itself have prevented an action or event from occurring. However, combined with other causes, it influenced the outcome of the action or event, either in occurrence or significance.

Direct cause. The factors or conditions leading to an undesirable event. Factors or conditions that if removed would have prevented the undesirable event.

Failure mode. "How" the inappropriate action or condition happened.

Failure scenario. A chronological series of events, or chain of events, that starts with an initiating event and ends with the observed consequences of the event.

Immediate action. Measures taken to fix the immediate problem and/or to mitigate its effects. Immediate actions are usually taken at the time of discovery of the event.

Inappropriate action. Human action, either observed or unobserved, that

- Resulted in an undesirable or unwanted condition/results
- Led the task or system outside its acceptable limits
- Was not desired by a set of rules or an external observer
- Was not necessarily the fault of the individual committing it.

Interim corrective action. Compensatory measures taken to mitigate and prevent recurrence of an event before permanent corrective actions.

Issue. An all-inclusive term used in reference to items, services, or processes that do not meet established requirements. A matter of concern that requires response that if not addressed can adversely affect the safety or quality of science, product or service delivery, safeguards and security, business, operations, environment or employee well being. **NOTE: Resolution of an issue may require more than one action.** An Issue can adversely affect established requirements in 1) safety and security, 2) Authorization Basis, 3) the University of California contract (specifically Appendix F Measures), or 4) federal regulations. Issues can result from a variety of sources including matters identified through:

- Audit, assessment, or inspection findings
- PAAA or Occurrence Report findings;
- Operational readiness reviews (ORR) or during facility modifications;
- Management walkarounds;
- Nested Safety and Security committees;
- Employee safety concerns, or
- Causal analysis of events.

Institutional issue — Issues that have or could have substantial adverse impacts on performance throughout the Laboratory, require substantial Laboratory resources for corrective action, or require broad senior management concurrence and support for improvement. Examples include the stand down of one or more major facilities, a programmatic breakdown of quality, safety, or environmental management systems, or serious accidents and incidents.

Local issue — Issues that can be effectively managed and resolved at the directorate level or below that are entered into the institutional tracking system for tracking, trending, and warehousing purposes only and to provide a comprehensive view of issues from throughout the Laboratory.

Issues Management Coordinator. A person designated and authorized by their respective AD or Division leader responsible for implementing the Institutional Issues Management program at the AD, Division or Group level.

Issue identifier. A person within the Laboratory that identifies an issue.

Institutional Issues Management Coordinator. A person designated and authorized by the Laboratory Director responsible for management and oversight of the Institutional Issues Management program.

Issues Management. A proactive, systematic management of issues that includes issue identification and communication, causal analysis, corrective action planning including application of resources, resolution, follow-up assessments, trend analysis, and reporting of existing and potential problems as defined previously in this document.

Issue owner. A manager, at the lowest level possible, with the authority and resources to correct an issue.

Issues Review Board. The Issues review Board (IRB) provides senior management ownership and oversight of the Laboratory's issues and corrective action management programs. The IRB is chartered pursuant to regulatory (10 CFR 830, Subpart A) and contractual (DOE-O-414.1A) requirements for establishing processes to detect and prevent problems.

Operability. The status of a system, structure, or component (SSC) to satisfy its intended function. If the SSC can't perform its intended function or its performance is degraded, actions need to occur to ameliorate the consequences of the degraded operability status.

Performance problem(s). The inability to fulfill a required task or function.

Programmatic cause. Deficiencies in administrative programs, procedures or their implementation that are not unique to a specific event. Programmatic causes may indicate the potential for similar problems to occur if not corrected.

Recurring and Repeat Events. An event or similar event that has occurred more than once during an earlier time period. The appropriate period of time to consider varies with the issue, which may be narrowly or broadly defined. For these reasons the term is subjective in nature. The events may have the same outcome and root cause as a previous event. Numerous non-consequential events may be an indicator of more significant problems. A recurring event may or may not be an adverse trend.

Remedial corrective action. "Broke-fix" actions designed to fix the broken component or correct the adverse condition. They are usually done to mitigate the immediate risk. These actions are also referred to as immediate actions.

Response. Management action to address an issue which can include an analysis that determines that no action is required.

Risk. The probability of occurrence times the consequences of the occurrence.

Root cause. The most basic reason that an event, failure or inappropriate action occurred and, if corrected, will prevent recurrence.

Validation. A determination that the completed corrective action(s) provided effective resolution of the issue.

Verification. A determination that the corrective action was completed, which is made by an organization independent of the manager and staff responsible for development, implementation, and closure of the corrective action.

5. Issues Management

5.1 Overview

Issues management is the proactive, systematic management of issues that includes issue identification and communication, causal analysis, corrective action planning including the application of resources, resolution, follow-up assessments, trend analysis, and reporting of existing and potential problems as defined previously in this document. **NOTE: Security Issues may follow the process prescribed in the Issues Management LIR and this LIG but the documentation of resolving security Issues should be reviewed for classification and not entered in the LANL Institutional tracking system.**

The following charts provide a general process flow for:

- **Issue screening, Chart A**
- **Institutional issues, Chart B**
- **Issues Review Board, Chart C**
- **Local issues, Chart D**

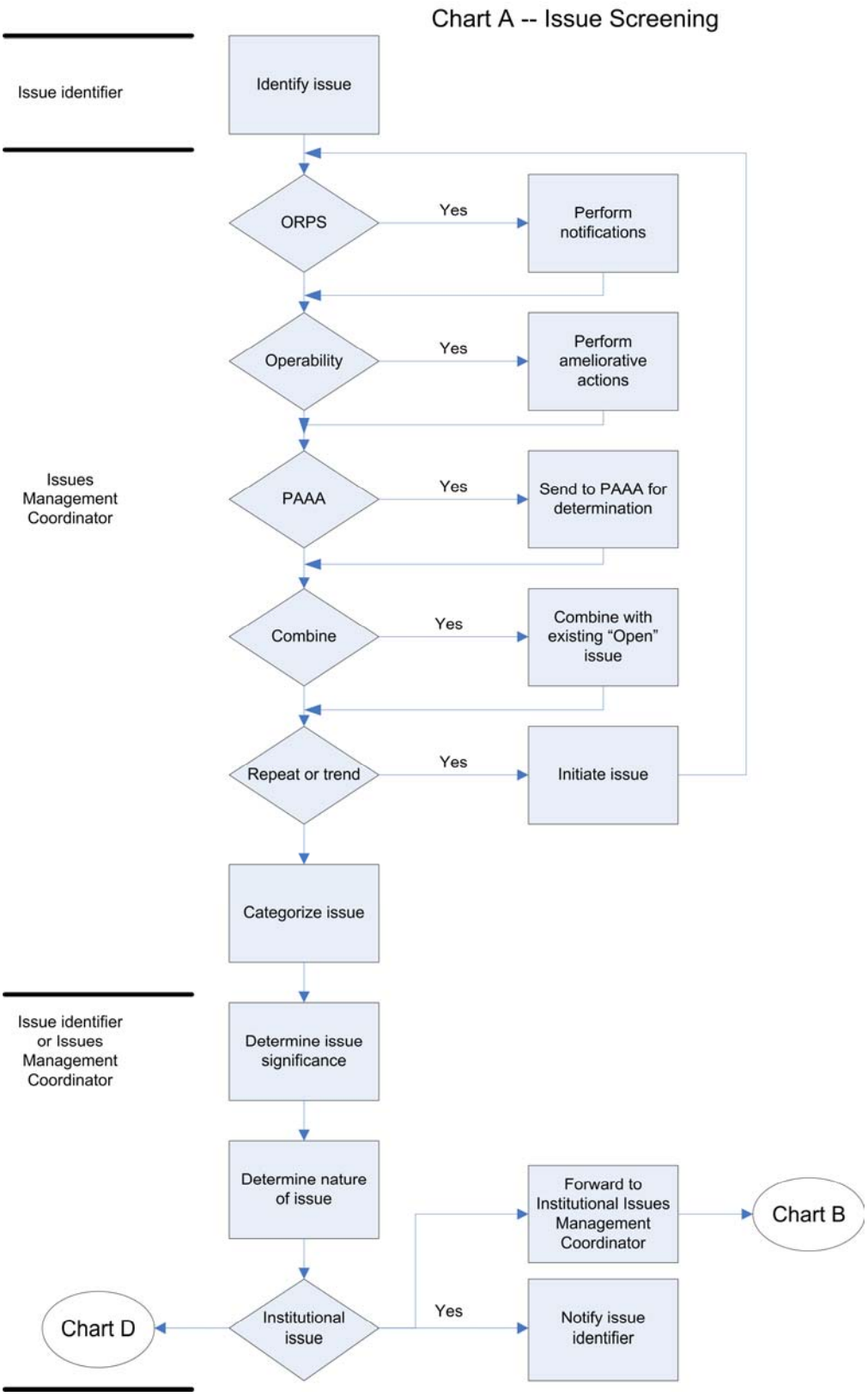


Chart A -- Issue Screening
Issue identifier
Identify issue
ORPS
Yes
Perform notifications
Operability
Yes
Perform ameliorative actions
Issues Management Coordinator
PAAA
Yes
Send to PAAA for determination
Combine
Yes
Combine with existing "Open" issue
Repeat or trend
Yes
Initiate issue
Categorize issue
Issue identifier or Issues Management Coordinator
Determine issue significance
Determine nature of issue
Forward to Institutional Issues Management Coordinator
Chart B
Chart D
Institutional issue
Yes
Notify issue identifier

Chart B – Institutional Issues Process

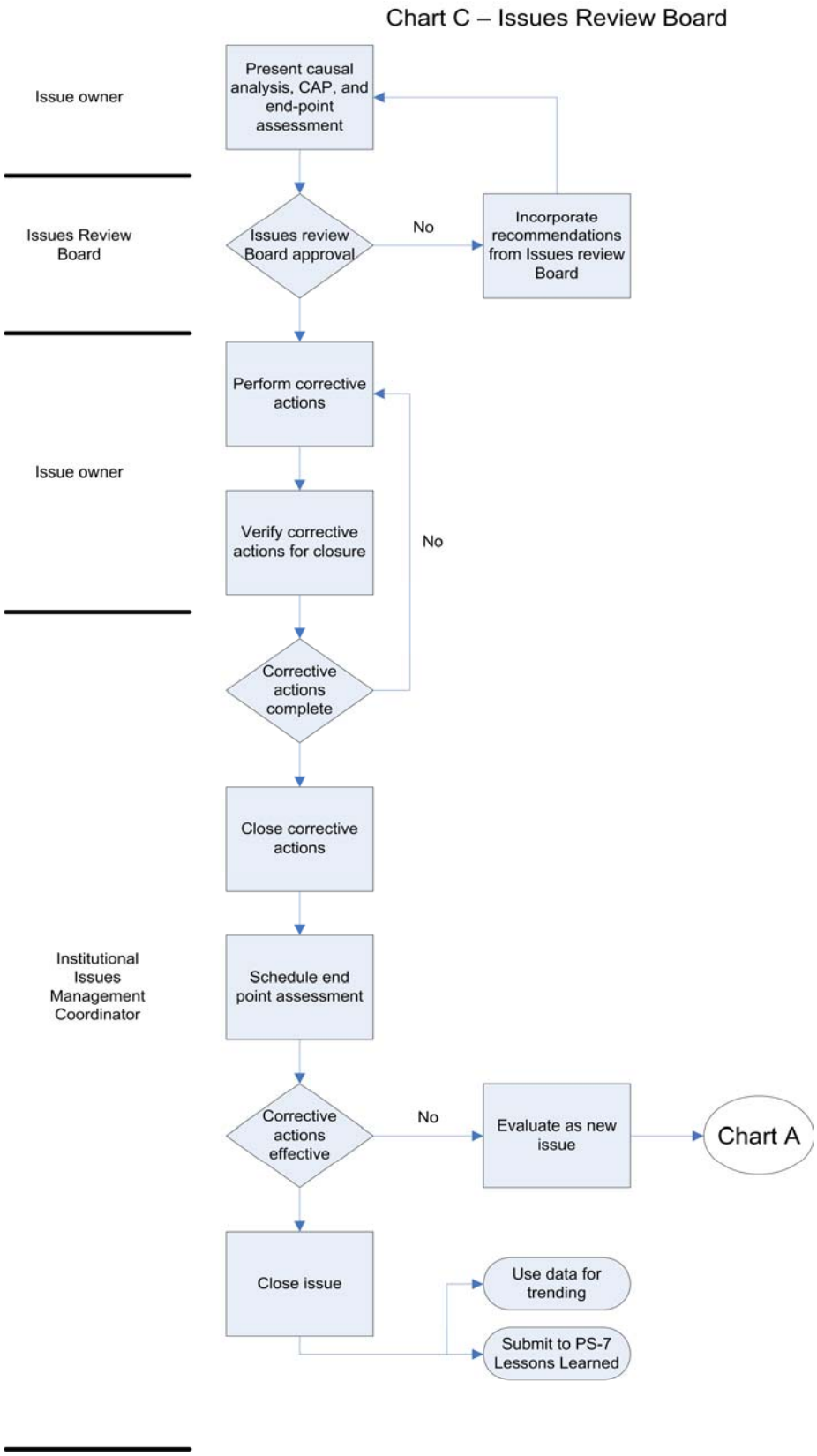
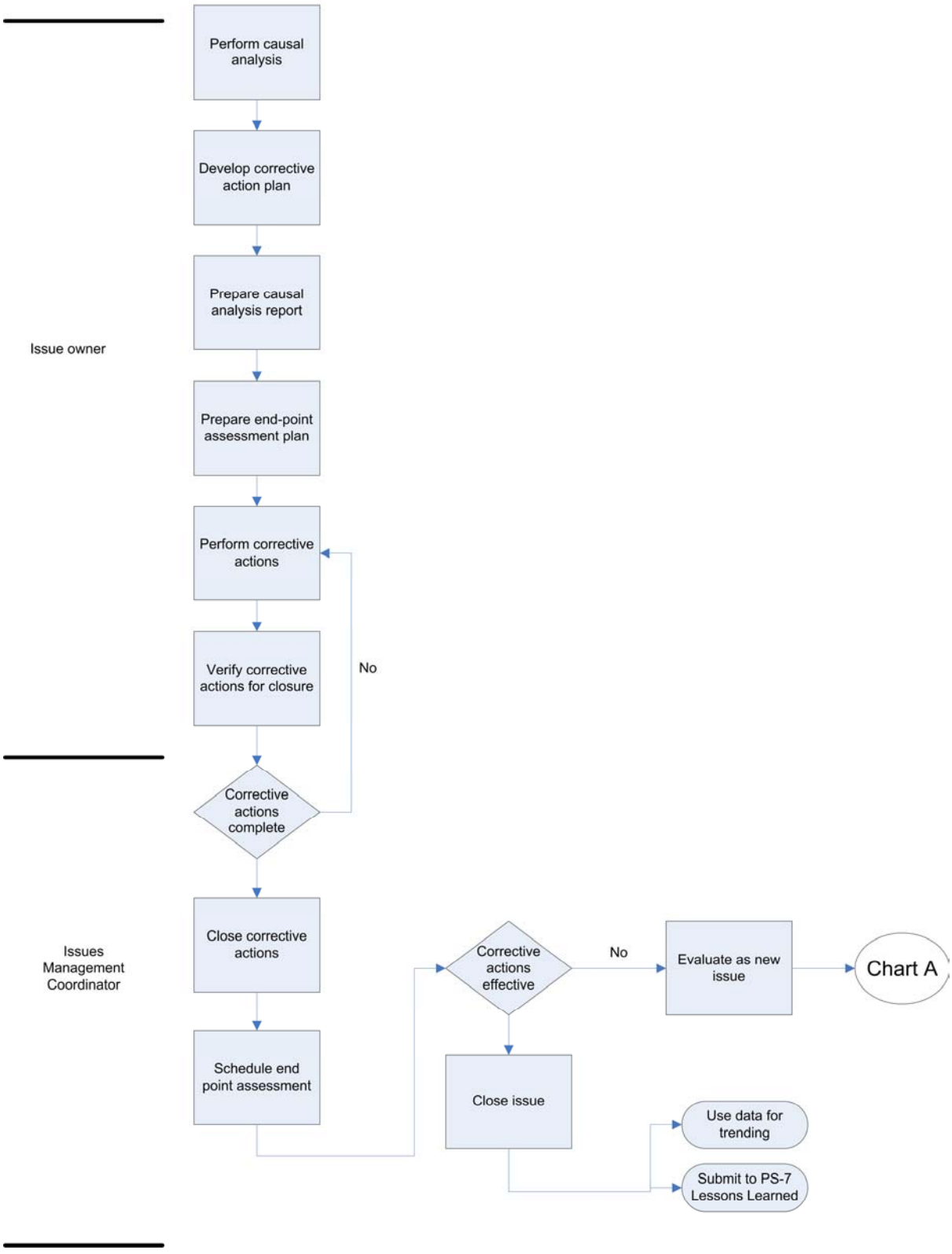


Chart C – Issues Review Board
Issue owner
Present causal analysis, CAP, and end-point assessment
Issues Review Board
Issues review Board approval
No
Incorporate recommendations from Issues review Board
Perform corrective actions
Issue owner
Verify corrective actions for closure
No
Corrective actions complete
Close corrective actions
Institutional Issues Management Coordinator
Schedule end point assessment
Corrective actions effective
No
Evaluate as new issue
Chart A
Close issue
Use data for trending
Submit to PS-7 Lessons Learned

Chart D – Local Issue Process



5.2 Setting up the issues management process

5.2.1 Issues Management Coordinator and the responsible manager should define and communicate Issues Management responsibilities in the organization. The organization should have an Issues Management Plan that clearly outlines the roles and responsibilities of the Issues Management Coordinator. Topics should include:

- How the plan fulfills the requirements of LIR 307-01-05.0,
- Designation and authorization of the Issues Management Coordinator by respective AD/Division leader
- Organization relationship within the management structure
- Training and qualifications of personnel who have responsibilities for issues management activities. Training and qualifications should be tailored to the complexity of the activities performed by the individual.
- How issues are identified and collected from employees and groups
- The periodicity for Issues Management Coordinator to meet with senior manager at the AD/Division level or management team to finalize decisions on issue analysis, categorization (local, institutional or issue documentation for tracking and trending purposes only), significance, prioritization and ownership; and provide status of issue closure, corrective action implementation, effectiveness of corrective action, tracking and trending and effectiveness of issues management program within the organization.

Note: At the discretion of the AD/Division level manager, the organization can either use a management team, issue review board or some such body as the designated body for screening or decision-making on issues. The AD/Division Leader for the respective organization however, should have an active and direct engagement in the final decision-making on issues to ensure that issue prioritization and corrective action management are fully integrated within the overall management and execution of the organization's activities and programs.

5.3 Issue identification and Entry into Institutional Tracking System

5.3.1 Issues Management Coordinator should identify steps required to enter data into the Institutional tracking system as each step in the

Issues Management process is completed. SEE the Institutional tracking system User's Manual provided by PS-7.

5.3.2 The issue identifier enters the issue into the Institutional tracking system. This activity may be retained by the Issues Management Coordinator for your organization. The Issues Management LIR identifies an example list of potential sources from which issues could be generated.

- Line-management Assessments (including management walkarounds, and Sub-reportable Events)
- Independent and Functional Assessments
- Employee Safety Concerns
- Nested Safety and Security Committee minutes
- Occurrence Investigations
- Radiological Incident Reports
- External Assessment
- Type A/B Investigation results
- Business practices updates
- Customer and stakeholder concerns
    - Conditions of approval for USQDs and Authorization Basis related Issues
    - Readiness assessment pre-start and post start Issues

5.3.3 The Issues Management Coordinator should determine at this time:

- If the issue is reportable to the DOE Occurrence Reporting and Processing System according to the severity thresholds in the "Laboratory Occurrence Reporting requirements/Guidance", Operations Support Tool 402-130-01. Assistance for this determination can be obtained by contacting PS-7. Click on the following link for the LANL Occurrence Reporting Matrix; **http://ps-7.lanl.gov/matrix/**

- If operability has been degraded and if required actions to ensure work place safety and plant stability have been implemented;

- If the issue is a potential Price Anderson Amendment Act (PAAA) noncompliance. LIR 308-00—07, "PAAA Enforcement Program Requirements," provides PAAA requirements and assistance can be obtained by contacting the LANL PAAA office, or the Facility PAAA coordinator. Click on the following link for PAAA checklists; **http://ps.lanl.gov/source/orgs/ps/paaa/checklists.shtml**

- If similar issues have occurred and consolidation of the current issue with open similar open issues can be done;

- If repetitive issues or potential trends exist;

- The issue category in accordance with section 5.7, Issue Categorization; and

5.3.4 The Issue identifier should determine the following:

- The significance of the issue in accordance with section 5.6, Significance Determination and Risk Management;

- The nature of the issue. Whether the issue is institutional or local in nature. The Issues Management Coordinator should identify potential opportunities, if any, to consolidate issues and provide for effective integrated corrective actions. Concurrence by the organization senior manager should also be enlisted. Determination of the issue nature should be entered into the institutional tracking system;

5.4 Institutional issues

If the Issue identifier or Issues Management Coordinator determines the issue is institutional in nature the Issues Management Coordinator should:

- Forward the issue to the Institutional Issues Management Coordinator (IIMC)

- Notify the Issue identifier of the status of the issue

5.4.1 The IIMC should:

- Schedule a meeting of the Issues Review Board for validation that the issue is institutional in nature.

- Assign an issue owner for the institutional issue in accordance with section 5.5, Assignment of Issue Owner

5.4.2 The institutional issue owner should:

- Determine the level of causal analysis rigor (**see the Issues Management Requirements Matrix**).

- Perform a root cause analysis, see Appendix B-1 through B-5, for guidance

- Develop a corrective action plan see Appendix B-6, for guidance

- Develop root cause analysis final report see Appendix B-7 for guidance

- Develop end point assessment plan see Appendix B-8 for Guidance

- Schedule a meeting with the IRB to present the causal analysis, the corrective action plan, and endpoint assessment plan to the IRB

5.4.3 The IRB should:

- Review the causal analysis, associated corrective action plan, and end point assessment plan for adequacy

- Approve or reject the causal analysis, corrective action plan, end point assessment plan, and offer suggestions to strengthen the case presented to them

5.4.4 The IIMC should:

- Reschedule another meeting with the IRB and the institutional issue owner if any of the information presented to IRB is rejected

- Enter the information presented to the IRB into the institutional tracking system if approved by the IRB.

5.5 Assignment of Issue Owner

5.5.1 The Issue identifier or the Issues Management Coordinator should assign an Issue Owner for local issues and should get the approval of the designated owner before documenting the assignment in the Institutional tracking system.

5.5.2 Institutional issue owners are assigned by the IIMC with concurrence of the IRB.

5.5.3 Each issue should be owned at a management level commensurate with the issue's overall significance, breadth of impact, and availability of resources.

5.5.4 When Issues are assigned outside of your organization, the Issue identifier should consult with the Issue Owner and provide the information to the appropriate AD, Division, and Group Level Issues Management Coordinator.

Note: Ownership of an issue does not indicate responsibility for determining or

implementation of the specific corrective action, but rather the responsibility and authority to direct the resolution process and assure effective and final resolution of the issue.

5.5.5 The Issue identifier or Issues Management Coordinator should gain concurrence from the assigned Issue Owner and document the concurrence in the institutional tracking system.

5.5.6 If concurrence cannot be easily achieved, the Issue should be elevated to the next level of management until concurrence is achieved.

5.6 Significance Determination and Risk Management

5.6.1 The Issue identifier or Issues Management Coordinator should determine the significance of the issue and enter it into the institutional tracking system. Appendix A provides guidance on significance determination including examples of consequences and the likelihood of the adverse consequences occurring. LIR 307-01-05, "Issues Management Program," defines the following levels of significance for identified issues.

5.6.2 The potential adverse consequence and likelihood of those adverse consequences occurring should be applied to determine the level of significance.

5.6.2.1 **High Significance Issue**: Severe potential risk that poses imminent hazard to worker health and safety, the public, the environment, security, regulatory compliance, facility operations, and/or program/business execution.

5.6.2.2 **Medium Significance Issue**: Moderate potential risk that poses a hazard to worker health and safety, the public, the environment, security, regulatory compliance, facility operations, and/or program/business execution.

5.6.2.3 **Low Significance Issue**: Minor potential risk that poses a low level hazard to worker health and safety, the public, the environment, security, regulatory compliance, facility operations, and/or program/business execution.

5.7 Issue Categorization

When Issue significance has been determined, the Issues Management Coordinator should categorize the issue as follows and enter the categorization into the Institutional tracking system.

Employee Safety Concern. Safety-or health-related issue that a Laboratory worker believes should be reviewed or corrected.

-
- Nuclear Safety Issue. Includes inadequacies in the following:

    - *Safety Basis* -- the documented safety analysis and hazard controls that provide reasonable assurance that a DOE nuclear facility can be operated safely in a manner that adequately protects workers, the public, and the environment.

    - *Safety Limits* -- the limits on process variables associated with those safety class physical barriers, generally passive, that are necessary for the intended facility function and that are required to guard against the uncontrolled release of radioactive materials.

    - *Safety management program* -- a program designed to ensure a facility is operated in a manner that adequately protects workers, the public, and the environment by covering a topic such as: quality assurance; maintenance of safety systems; personnel training; conduct of operations; inadvertent criticality protection; emergency preparedness; fire protection; waste management; or radiological protection of workers, the public, and the environment.

    - *Safety structures, systems, and components* -- both safety class structures, systems, and components and safety significant structures, systems, and components.

    - Quality -- the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

    - *Quality assurance* -- all those actions that provide confidence that quality is achieved.

    - *Quality Assurance Program (QAP)* -- the overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

- Policy Issue. Inadequacies in UC-LANL governing policies, institutional implementation policies and procedures, and Division, Program, project, group, or facility procedures issued by UC-LANL to accomplish its mission. This also includes Business Practice implementation. Issues identified from sources such as LANL Alerts and Notices should also be included.

    - *Governing Policies* – high-level policies issued by the Director that govern Laboratory work across the institution.

- *Institutional implementation policies and procedures* – policies issued by the Director's Office or Directorates on specific topics. These are derived from the Governing Policies.

- *Division, Program, Project, Group, or Facility Procedures* – procedures, standards, and work instructions that are issued by specific organizations for work that is done by or for that organization. These are issued by the relevant office as needed to direct or manage its work.

-
- Resource Management Issue. The lack of or inadequate management of personnel, finances, technology, the environment, cultural, material, or equipment employed to fulfill UC-LANL's mission.

- Programmatic Issue. The lack of or inadequacy of part of a program. (E.g. Nuclear Safety, Quality Assurance, Environmental, Security, or Information management).

- Deficiency. The lack of fulfillment of a requirement.

- Non-conforming Item. An item exhibiting a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

  Reportable Occurrence. An abnormal event or condition that is reportable to the DOE Occurrence Reporting and Processing System according to the severity thresholds in the "Laboratory Occurrence Reporting Requirements/Guidance". The types of reportable occurrences involve, but are not limited to, facility conditions; environmental concerns; personnel safety; radiological protection; safeguards and security; transportation; loss or damage to DOE property; defective items, materials, or services (including counterfeit/suspect parts); nuclear explosive events; and cross-category items to include related occurrences, near-miss events, and potential concerns. **Note: Some Issues may be Reportable under other systems such as the DOE Occurrence Reporting and Processing System (ORPS) or the Price-Anderson Amendment Act Noncompliance Tracking System (NTS). In these cases reference should be made to these systems and corresponding tracking numbers.**

5.8 Causal Analysis and Corrective Action Planning
The Issue Owner should
- Perform causal analysis and prepare an action plan, per the Issues Management Requirements matrix below,
- Assign responsibility for causal analysis, individual actions, and assure that responsibility is accepted, and
- Ensure the results of the following are entered into the Institutional tracking system as appropriate:
  - Causal Analysis and Corrective Action Planning,

- Corrective Action Closure,
- Corrective Action/Issue Closure Verification, and
- End Point Assessment/Validation.

Appendix B provides guidance on:

- Causal Analysis and Corrective Action Planning,
- Corrective Action Closure,
- Corrective Action/Issue Closure and Verification, and
- End Point Assessment/Validation.

Note: The Action Responsible Person(s) should be involved in the development of the plan and the plan should specify the action to be taken, a target date for completion, and the person responsible. LIR 307-01-05 provides requirements for causal analysis, corrective action development, and validation of corrective action effectiveness.

ISSUES MANAGEMENT REQUIREMENTS MATRIX				
		Issue Significance Level		
Activity	**Responsibility**	**High**	**Medium**	**Low**
Assignment of responsibility for resolution	Issue Owner*	All significance levels		
Root Cause Analysis**	Issue Owner	Required	Optional***	Optional***
Apparent Root Cause Coding	Issue Owner	Required	Required	Required
Action plan development	Issue Owner	Required	Required	Optional***
Tracking of actions to closure	Issue Owner	Required	Required	Optional***
Documentation of Closure	Issue Owner	Required	Required	Optional***
Validation of effectiveness of resolution	Issue Owner	Required	Optional***	Optional***
Trending, analysis, synthesis of data and reporting to senior management	Issues Management Coordinator	Quarterly or as required by senior managers	Quarterly by Issues Management Coordinator or as required by senior managers	Quarterly by Issues Management Coordinator or as required by senior managers
Obtain approval for changes to corrective action plans, due dates, and interim measures	Issue Owner	Required for all issues	Required for Institutional or external issues	Required for Institutional or external issues
Independent Review of Closure and validation of effectiveness	Issues Management Coordinator	Performed on selected sample of issues or as required by external agencies	Optional***	Optional***

* All activities should be the overall responsibility of the Issue Owner unless other wise indicated; however, Issue Owners may formally delegate specific actions and document the delegation in the Institutional tracking system.
** Assistance for root cause analysis may be obtained from PS-7.
*** Optional unless required by an external agency

5.9 Reporting

5.9.1 Issues Management Coordinators should provide their respective management with reports providing the status of issues and action items. The status of issues should be reported in quarterly self-assessments, Nested Safety & Security Committee Program roll up presentations, and trend reports. Suggested information provided by Issues Management Coordinators to their management include:

- Status of open, delinquent, and closed issues and actions
- Issues requiring causal analysis and corrective action plans
- Pareto charts displaying issues by issue categorization and significance
- Run charts displaying performance over time
- Identified emerging Issues

Reports should provide a performance goal, analysis of the issues, causes, and effectiveness of corrective actions, lessons learned, and suggestions to bring issues to closure and meet performance goals.

5.9.2 Issues Management Coordinators should meet with their management on a frequent basis to ensure issues are addressed in a timely manner.

5.10 Lessons learned

5.10.1 The Issues Management Coordinator should communicate lessons learned to other LANL organizations via PS-7.

5.11 Issues Change Control

5.11.1 Issues Management Coordinators should contact the respective issue change contact provided in **Table 1** to initiate changes to issues such as issue and action due dates, corrective actions, changes in responsibility, and submittal of closure documentation. When changes are made to an action or issue, this communication should be documented within the LANL Issues Tracking System.

5.11.2 Some issues require concurrence from the initiating organization for changes to action completion dates and submittal of closure documentation. Document concurrence with the change in the Institutional tracking system.

ISSUES CHANGE CONTROL CONTACTS

Issue Initiator	Issue Change Contact (change target date, nature of action, or submit closure documentation)
DOE Headquarters	Institutional Issues Management Coordinator/IRB
DOE Albuquerque	Institutional Issues Management Coordinator/IRB
DOE LAAO	Institutional Issues Management Coordinator/IRB
DNFSB	Institutional Issues Management Coordinator/IRB
NMED	Institutional Issues Management Coordinator/IRB
Lab wide Independent Assessments (External)	Institutional Issues Management Coordinator/IRB
DOT Issues	Institutional Issues Management Coordinator/IRB
DoD	Institutional Issues Management Coordinator/IRB
University of California Assessments	Institutional Issues Management Coordinator/IRB
Internal Audits and Assessments (AA-2)	AA-2 Audit Team Leader
Administrative, Legal and Fiscal Assessments (AA-3)	AA-3 Audit Team Leader
Institutional Quality Assessments (PS-1)	PS-1 Trigger Coordinator/POC
Safety Basis Office (PS-4)	PS-4 Trigger Coordinator/ POC
ORPS (PS-7	PS-7 Trigger Coordinator/ POC
PAAA (PS-PAAA)	PS-PAAA Trigger Coordinator/ POC
MWA	Local Line Management
Facility/Programmatic Independent Assessments (External or Internal requested by facility/program and excluding reviews by RSC and NCSC and AA Groups)	Division Issues Management Coordinator
Reactor Safety Committee (Director's cross organizational committee)	Trigger Coordinator/ POC (Committee Chair.)
Nuclear Criticality Safety Committee (Director's cross organizational committee)	Trigger Coordinator/ POC (Committee Chair.)
Materials Control and Accountability (S-4)	S-4 Trigger Coordinator/ POC
Division/Program Management Assessments	Division Issues Management Coordinator
Fire Protection	FWO-Fire Trigger Coordinator/POC
Packaging and Transportation	SUP-5 Trigger Coordinator/POC
DOE Facility Coordinator	Division Issues Management Coordinator
Authorization Basis Change Conditions of Approval	Safety Basis Office (usually tracked in local domain, but resolution with DOE/SABT is through SBO)
Local Incident (Incident Reports, Nonconformance Reports, etc.)	Local Issues Management Coordinator

Table 1

6. Documentation

Records produced from implementing this LIG include:

- Identified Issues including significance determination, categorization, and ownership responsibility
- Causal Analysis documentation
- Corrective action plan documentation
- Evidence corrective actions have been completed including closure verification documentation
- Effectiveness assessment documentation

7. References

- PS-7 is the OIC for this LIG (665-8690).
- 10 CFR 830 Subpart A, "Quality Assurance Requirements"
- DOE O 414.1A**, "**Quality Assurance"
- Issues Management Program, LANL, LIR 307-01-05.0
- Performance Assurance, LANL, LPR307-01-00.
- Management Safety Walk-Arounds, LANL, LIR307-01-03.
- Management Assessment Program, LANL, LIR 307-01-01.
- Laboratory Records Management, LANL, LIR 308-00-02.

8. Attachments

Appendix A, Guidance on Significance Determination
Appendix B, Causal Analysis and Corrective Action Planning
Appendix B-1, Change Analysis
Appendix B-2, Barrier Analysis
Appendix B-3, Event and Causal Factor Charting
Appendix B-4, Fault Tree Analysis
Appendix B-5, Task Analysis
Appendix B-6, Corrective Action Plan Development
Appendix B-7, Causal Analysis Report Template
Appendix B-8, Corrective Action Closure
Suggested End Point Assessment Format
Sample Issues Management Coordinator Appointment Letter

APPENDIX A
Guidance on Significance Determination

	Likelihood				
Consequence	**Frequent** Usual occurrence to likely occurrence, reasonably expected	**Probable** Likely occurrence to irregular occurrence, infrequently expected	**Occasional** Irregular occurrence, to infrequent, slight chance of occurrence	**Improbable** Slight chance of occurrence to Highly unlikely occurrence	**Remote** Highly unlikely occurrence to Extremely unlikely occurrence
Catastrophic Death, severe injury, occupational illness, severe environmental harm or liability, severe property damage, or inability to complete mission objectives	High	High	High	Medium	Low
Critical major injury, chronic impairment or occupational illness, major environmental harm or liability, major property damage, or major impairment to completing mission objectives	High	High	Medium	Low	Low
Moderate minor injury, temporary impairment or occupational illness, minor environmental harm or liability, minor property damage, or to delay in completing mission objectives	High	Medium	Low	Low	Low
Negligible Less-than-minor injury or occupational illness, less-than minor environmental harm or liability, less-than-minor property damage, or less-than-minor delay in completing mission objectives	Low	Low	Low	Low	Low

APPENDIX B
CAUSAL ANALYSIS AND CORRECTIVE ACTION PLANNING GUIDANCE

Data gathering

1. Determine if prior investigation of the event has occurred and get information generated as a result of the investigation such as a report, interview statements, pictures, drawing, etc.

2. Information that should be of interest to the team consists of establishing conditions before, during, and after events; personnel involvement (including action taken); environmental factors; and other information having relevance to the condition or problem.

3. Photographs of the event area from several views may be useful in analyzing information developed during investigation.

4. Every effort should be made to preserve the event scene. Physical evidence, such as failed components, ruptured gaskets, including partially completed work orders, and associated procedures, etc., should be retained as appropriate. Establishing quarantine areas, or the tagging and segregation of pieces and material, should be performed for failed equipment or components. This should be done despite operational pressures to restore equipment to service.

5. Event participants and other knowledgeable individuals should be identified.

6. Once the data associated with this event has been collected, it should be verified to ensure accuracy. Methods of data verification include using corroborating witness statements, empirical data obtain from a different source, peer reviewed literature, procedure and record reviews, and the use of subject matter experts.

7. If the event involves a process breakdown, get as much information on the processes or programs in place to construct a process flow diagram. A process breakdown could be: a failure to perform a task, an engineering evaluation that results in improper or unsupported design output, a process/procedure that routinely results in an undesired outcome, etc.

8. The following process steps will take you through the cause analysis development process, providing the team with systematic methods and techniques, as well as expected deliverables.

Determining What Information is Needed.

Some areas to be considered are:

- Activities related to the event or condition
- Initial or recurring problem

- Hardware (equipment) or software (programmatic- type issues) associated with the event
- Recent program or equipment changes
- Physical environment or circumstances.

Methods of Gathering Information

1. Interviews/statements - Interviews should be fact finding and not fault finding. Preparation of questions before the interview is essential to ensure that necessary information is obtained.

   Interviews should be conducted, preferably in person, with those people who are most familiar with the problem. Individual statements could be obtained if time and/or the number of personnel involved make interviewing impractical. Interviews should be documented using any format desired by the interviewer. Consider conducting a "walk-through" as part of this interview if time permits.

   Although preparing for the interview is important, it should not delay prompt contact with participants and witnesses. The first interview may consist solely of hearing their narrative. A second, more detailed interview can be arranged, if needed. The analyst should always consider the interviewee's objectivity and frame of reference.

2. Interviewing others - You may want to interview other personnel who have performed the job in the past. Consider using a "walk-through" as part of the interview.

3. Reviewing records - Review relevant documents or portions of documents as necessary and reference their use in support of the root cause analysis. Record appropriate dates and times associated with the event on the documents reviewed. Examples of documents include the following:

   - Operating logs
   - Inspection/surveillance records
   - Meeting minutes
   - Procedures and instructions
   - Drawings and specifications
   - Functional retest specification and results
   - Design basis information
   - Related quality control evaluation reports
   - Trend charts and graphs
   - Correspondence
   - Maintenance records
   - Computer process data
   - Vendor manuals
   - Equipment history records
   - FSAR/technical specifications
   - Radiological surveys
   - Plant parameter readings
   - Work order
   - Sample analysis and results (chemistry, radiological, air, etc.).

4. Acquiring related information - Some additional information that an evaluator should consider when analyzing the cause(s) includes the following:

    - Evaluating the need for laboratory tests, such as destructive/nondestructive failure analysis.
    - Reviewing physical layout of system, component, or work area; developing layout sketches of the area; and taking photographs to better understand the condition.
    - Determining if industry operating experience information exists for similar events at other plants.
    - Reviewing equipment supplier and manufacturer records to determine if correspondence has been received addressing this problem.

Data Review

The primary objective of data review is to determine whether additional information is needed before event analysis. The interactive nature of the process and how it works in one area may lead to further development issues in another area.

To effectively accomplish data review, focus on the key issues. Some key issues to be considered are:

- Consequence of the event in relation to environmental safety, plant or equipment reliability, personnel safety, and Laboratory mission accomplishment.
- Sequence of occurrences or multiple failures during the event.
- Recurring operational, maintenance, and human performance problems, equipment failures, and organizational and programmatic inadequacies.
- Unexpected condition encountered during the event.
- Actual or potential consequence of the event.
- Previous corrective actions taken by the site for similar events.
- An event involving a process breakdown such as a failure to perform a task.
- An engineering evaluation that results in improper or unsupported design output.
- A process/procedure that routinely results in an undesired outcome.

APPENDIX B-1
CHANGE ANALYSIS

Overview

Change analysis is a process that can be used to determine the root or contributing causal factors of events. The process enables the problem solver to establish what has changed that contributed to an Issue. The determination that contributing event factors are due to a change in some practice can lead the investigator to better conclusions involving required corrective actions. In a proactive application opportunities for improvement can be identified before an Issue surfaces.

The fundamental process of change analysis involves six steps. These are: situational determination, determination of a similar but event free situation, comparison of both situations, recording of dissimilarities, analysis of differences for impact on the event and incorporating these differences into contributing causal factors.

1. Situational Determination

   Evaluation of the situation surrounding the event is critical to the change analysis process. Emphasis should be placed upon determining possible contributors to the event. These include: time of event, personnel, equipment, procedures, physical surroundings, event severity, etc.

2. Similar But Event Free Event Determination (Non-Event)

   Evaluate similar situations where a problem or event did not occur while performing work activities or during facility operations. If possible, choose a situation where the majority of contributors are the same. Using Subject Matter Experts an evaluation of an event free situation can also provide insight into what contributed to the event.

3. Comparison Of Both Situations

   Compare the event situation with the non-event situation. Look for dissimilarities in event and non-event contributors. Be careful to consider all differences no matter how insignificant that they may appear.

4. Write Down All Differences

   Dissimilarities between the event and non-event situations should be written down. It is preferable to group differences under major contributing categories.

5. Analyze The Differences For Effect On The Event

   Differences between the events may be as obvious as the time of day or as nebulous as the same instructions being given by a different person. Each difference should be individually dissected for its impact on the event.

6. Incorporate Contributing Differences Into The Event Causal Factors (Probable Cause)

Contributing differences are caused by a change in some practice. The investigator should determine what mechanism created this change. Once identified, this change should be altered or eliminated to prevent recurrence.

Change Analysis Work Sheet

Change Factor	Event	Non-Event	Difference/ Change	Effect	Probable Cause
WHAT • Conditions • Activities • Equipment					
WHEN • Occurrences • Plant status • Work schedule					
WHERE • Physical location occurred • Environmental conditions • Steps of procedure					
HOW • Work practice • Omission • Extraneous action • Out of sequence • Poor procedures					
WHO • Personnel involved • Supervision					

Change Analysis Example

CHANGE FACTOR	EVENT	NON-EVENT	DIFFERENCE/ CHANGE	EFFECT	Probable Cause
WHAT • Conditions • Activities • Equipment	Unexpected water (3-5 gallons) discharge from piping system upon breach of system with a drill	Minimal water (Tsp.) found in pipe system upon breach of system.	Piping system retained water.	Resulted in an uncontrolled release of contaminated fluids.	
WHEN • Occurrences • Plant status • Work schedule	After installation of the Over Ground Transfer Line (OGT)	In support of installation of the OGT	The OGT was installed differently than the original piping design.	The new system configuration had a loop seal.	
HOW • Work practice • Omission • Extraneous action • Out of sequence • Poor procedures	System was breached after it was “Flushed & Drained”	System was breached after it was “Flushed & Drained”	System configuration was not the same.	The new system configuration had a loop seal in the system.	
WHO • Personnel involved • Supervision	The same Maintenance Supervisor that installed the OGT Cognizant Engineer RadCon Engineer Operations Manager	The same Maintenance Supervisor that drilled into OGT Cognizant Engineer RadCon Engineer Operations Manager	For the OGT removal, the Cognizant Engineer was not involved with the planning due to the rated risk assessment of the job.	Without the Cognizant engineer involved with the planning, the opportunity to communicate/ interpret drawing information into work impact concerns was missed.	

APPENDIX B-2
BARRIER ANALYSIS

Barrier analysis is the process of determining the adequacy of barriers and their ability to prevent and energy source from coming in contact with something of value and adversely affecting it, creating an undesirable condition or situation. Examples of engineered or hard barriers include shielding when working with radioactive material or hazardous chemicals, or dielectric gloves worn when working around high voltage electrical lines. Other examples include the use of administrative or soft barriers such as procedures and integrated work documents.

When performing a barrier analysis, start with the undesirable condition or situation and identify the barriers that should be in place to prevent the condition. Make a determination of whether the barriers performed their intended functions. Trace the energy flow backwards from barrier to barrier until a cause is found that if corrected would have stopped the undesirable condition from occurring.

There are many elements that should be addressed during the performance of a barrier analysis. The questions listed below are designed to aid you in determining what barrier failed causing a thing of value (target) to be adversely affected.

1. What barriers existed between the second, third, etc., condition/situation and the second, third, etc., failures?

2. If there were barriers, did they perform their functions? Why?

3. Did the presence of any barriers mitigate or increase the event severity? Why?

4. Were any barriers not functioning as designed? Why?

5. Was the barrier design adequate? Why?

6. Were there any barriers on the condition/situation source(s)? Did they fail? Why?

7. Were there any barriers on the affected component(s)? Did they fail? Why?

8. Were the barriers adequately maintained?

9. Were the barriers inspected before expected use?

10. Why were any unwanted energies present?

11. Is the affected system/component designed to withstand the condition/situation without the barriers? Why?

12. What design changes could have prevented the unwanted flow of energy? Why?

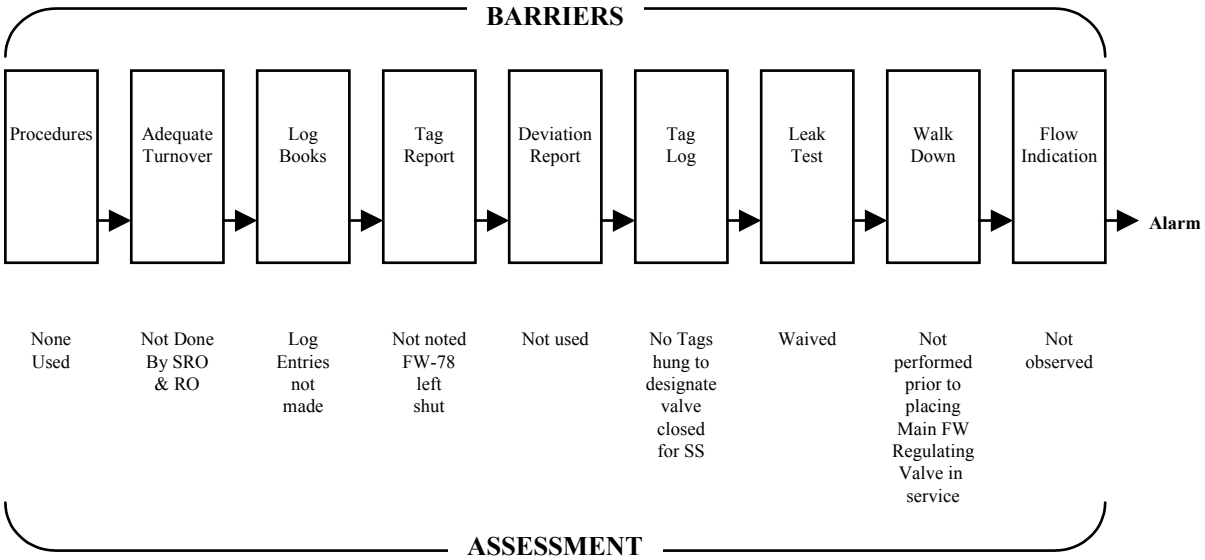
13. What operating changes could have prevented the unwanted flow of energy? Why?
14. What maintenance changes could have prevented the unwanted flow of energy? Why?
15. Could the unwanted energy have been deflected or evaded? Why?
16. What other controls are the barriers subject to? Why?
17. Was this event foreseen by the designers, operators, maintainers, anyone?
18. Is it possible to have foreseen the event? Why?
19. Is it practical to have taken further steps to reduce the risk of the event occurring?
20. Can this reasoning be extended to other similar systems/components?
21. Were adequate human factors considered in the design of the equipment?
22. What additional human factors could be added? Should be added?
23. Is the system/component user-friendly?
24. Is the system/component adequately labeled for ease of operation?
25. Is there sufficient technical information for operating the component properly? How do you know?
26. Is there sufficient technical information for maintaining the component properly? How do you know?
27. Did the environment mitigate or increase the severity of the event? Why?
28. What changes were made to the system/component immediately after the event?
29. What changes are planned? What changes might be made?
30. Have these changes been properly, adequately analyzed for effect?
31. What related changes to operations and maintenance have to be made now?
32. Are expected changes cost-effective? Why? How do you know?
33. What would you have done differently to prevent the event, disregarding economic considerations (as regards operation, maintenance, and design)?

34. What would you have done differently to prevent the event, considering economic concerns (as regards operation, maintenance, and design)?

EXAMPLE

In this actual situation, the operating crew shift supervisor decides to leave a manual recirculation pump isolation valve closed because the main recirculation pump regulating valve was leaking, making it difficult to control flow rate. Subsequently, as the operation crew continued waste transfer, an alarm sounded before the problem was diagnosed and corrected. Prior to this, recirculation pump was being supplied through the un-isolated bypass line.

Barrier Analysis



APPENDIX B-3
EVENT AND CAUSAL FACTOR CHARTING

Event Analysis
Event analysis identifies the apparent cause(s). The depth of this analysis should be commensurate with event significance/complexity process, problem or event. Event Analysis may use a combination of a timeline and a process flow determination.

Overview

1. Event and Causal Factor (E&CF) Charting is used to assist the investigator in understanding the sequence of events and causes which led to the incident under investigation. Major events are not usually the result of single failures but are the result of complex conditions that have evolved over a period of time and involve multiple work groups, systems, tasks and/or components.

2. E&CF charting is very useful for evaluating complex events. It can be used to show the exact sequence of events from start to finish, including broken barriers, pre-existing conditions, secondary events, inappropriate actions and causal factors that produced and shaped the event.

3. E&CF charting is an analytical technique or tool, it is not intended that the user become bogged down or overly burdened with the precise details of structuring and drawing the chart. Understanding and using the organizational and analytical concepts of the technique are more important.

4. The E&CF chart is a graphically displayed flow chart of an entire event. The heart of the E&CF chart is the sequence of events and facts plotted on a time line.

    - The beginning and ending points should be selected to capture the essential information pertinent to the situation.

    - As the primary event line is established, additional situation features, such as related conditions, secondary events, and presumptions, should be added.

    - Probable causal factors become evident as the chart is developed; often causal factors that were not obvious at the outset become evident through this technique.

    - E&CF charts are particularly useful for complex and complicated situations and are more meaningful than long narrative descriptions.

    - The E&CF chart provides an excellent opportunity to graphically display barriers, changes, cause and effect, and to show how they were involved in equipment and human performance situations.

    - It is important to understand the difference between the HOWs and WHYs of a situation. The HOW aspect generally identifies the mechanism that created the

situation, i.e. an equipment/human performance condition, or E&CF primary effects and conditions.

- The WHYs analyze the HOW aspects for the reason the inappropriate action or condition occurred. For this reason, it is important to identify the HOWs of a situation, otherwise some of the WHYs may be missed. Internal and external causal and situational information needed for the E&CF chart can be identified through interviewing along with other analytical techniques such as change, barrier, and fault tree analysis.

- E&CF charting, identifies the cause(s), i.e. the WHYs, for each of the primary effects or conditions, the HOWs. In most situations determining a more detailed cause requires an iterative cause-and-effect process by treating the previous cause as an effect, i.e. the adverse condition Y that cause an event Y is actually the result of another event X. The most precise cause applicable to the situation, indicates where plant specific corrective actions are needed.

- E&CF charting is particularly good for situations involving equipment and human performance events in which the behavioral aspects are important. The technique can serve as a guide in directing the course of the evaluation and therefore it should be applied early in the task to get the most benefit. The chart is also very effective in illustrating the final report findings and conclusions. Corrective action(s) should be derived for each primary cause and for each secondary cause as warranted.

5. E&CF charting contributes the following to an effective evaluation:

- Organizes situations and applicable data involved with the analysis.

- Shows the sequence of events from beginning to end. Presents the situation in a single glance (big picture).

- Stimulates development of other conditions, secondary events, presumptions, causal factors, changes, primary events, and control barriers.

- Include results from other analyses. These results may expand the sequence of events, and provide more meaningful information.

- Provides cause-oriented explanations of the situation and inappropriate actions.

- Helps ensure objectivity.

- Provides a basis for beneficial changes to prevent future similar inappropriate actions.

Practical Application

The experience of many people participating in numerous causal evaluations has led to the identification of six key elements in the practical application of E&CF charting to achieve high quality evaluations.

1. Begin early. As soon as the accumulation of factual information related to the event starts, begin construction of preliminary event sequence line with known primary events/happenings.

2. Proceed logically with available data. Events and cause factors usually do not emerge during the investigation in the sequential order in which they occurred. Initially, there will be many holes and deficiencies in the chart. Efforts to fill these holes and accurately track the event sequence and their contributing conditions will lead to deeper probing by evaluators which will uncover the true facts involved. In proceeding logically, it is usually easiest to use the last event as the starting point and reconstruct the pre-event and post event sequences from that vantage point.

3. Use an easily updated format - flow charting software (e.g. Visio or MS Word Draw) or simply create by hand using Post-It Notes on a large sheet of paper. As the primary event line is established, additional situational features (such as related conditions, secondary events, barriers and presumptive conditions) are added.

4. Gather facts using other evaluation techniques. Include the results of these techniques on the chart.

5. Develop conditions and causal factors to a greater detail. Include results of other evaluations techniques. Decide which actions are inappropriate.

6. Validate causes and conditions with results from other techniques.

Definitions used with Event & Causal Factor Charting

1. Primary Events - actions or happenings directly leading up to or following the undesirable event. Events should be described with one subject and one verb, i.e., "hose ruptured" is an undesirable event versus "hose has a crack" which describes a condition.

2. Secondary Events - actions or happenings that impacted the primary event but are not directly involved in the undesired event.

3. Terminal Event - the end point of the evaluation. This is usually what is being evaluated, fire, tank rupture, unit shutdown etc. The terminal event may appear at the middle of the chart to provide pre and post event information.

4. Presumptive Event - action or happening that is assumed because it appears logical in the sequence but cannot be proven.

CAUTION:

Use presumptive events sparingly. These events are speculated and may have to be proven with facts or analysis.

5. Presumptive Condition/Causal Condition - a factor or condition that cannot be proven but is assumed, because it appears to logically affect another condition or event.

6. Primary Effect - an undesirable event or happening that was critical for the situation being evaluated to occur. Primary effects are those events that should not have occurred, equipment failure, inappropriate action, etc.

E&CF Charting Process – (see figures included in this section)

1. Define the scope of the chart from initial information. Construct preliminary event line with known primary events. Each event should describe a single action or happening and should be precisely written using a short sentence containing one noun and one action verb. Each event should be derived logically from the one(s) preceding it and should be based on factual, valid information, otherwise it should be enclosed in a dotted box or oval indicating it is an assumption.

   - Identify the beginning point
   - Identify the terminal event
   - Add other known primary events to develop a timeline for the event ("Primary Event Line").

2. Evaluate initial information and documentation. Add known presumptive conditions to construct the preliminary event and causal factor chart.

3. Gather additional facts to complete the story or as questions arise from the chart construction.

4. Develop the chart representations of conditions and causal factors to a greater detail.
   a. Identify those events that should not have occurred and were both inappropriate and essential to the development of the undesirable event (primary effects). Events should describe a single action using a short sentence containing a subject followed by an active verb and action, e.g., Who Did What. Do not use vague passive voice. If we do not know who the subject was, use a question mark and find out later. Be sure to change the individual names to job titles for the final report.

   b. Examine each primary effect and determine what conditions or causes allowed them to occur.

   c. For each condition identified, determine why that condition existed. Treat the condition as an effect and determine the cause for the effect. Identify conditions at the

outset of the event, during the course of the event and following the course of the event. Add these to the chart as ovals.

1.) Identify the factors causing or contributing to the outcome. Use cause and effect analysis to help identify relationships that exist around a primary effect to help identify contributing and root causes. Cause and effects analysis is based on the following principles:

- Undesirable events (equipment failures, human performance problems, etc.) are the effects of some cause (e.g., contributing cause or root cause)

- Undesirable events are caused to happen as a result of plant conditions, design, human performance, etc.

2.) For each condition (effect) identified, determine why it occurred (cause). The root cause(s) of an event can be determined by examining the cause and effect relationships that surround the primary effects (e.g., undesired event). For example, "the hose had a crack" is a statement of a condition (effect), “why” the hose had a crack would lead to the cause of the condition (cause, root cause).

3.) Physical and/or administrative barriers that were broken should be noted on the chart as broken bars.

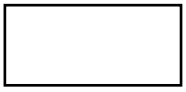
4.) Ensure facts support conclusion.

5. Continue to investigate and develop the chart until one of the following limits is reached:

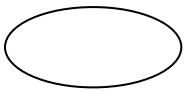
- The cause is outside the control of the plant staff
- The correction of the cause is determined to be cost prohibitive
- The primary effect is fully explained
- There are no other causes that explain the effect being evaluated.

Recommended Event & Causal Factors Diagram Symbols

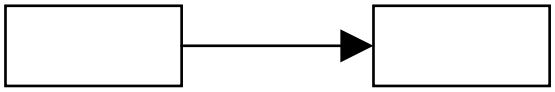
1. Enclose all events (actions or happenings) in rectangles.



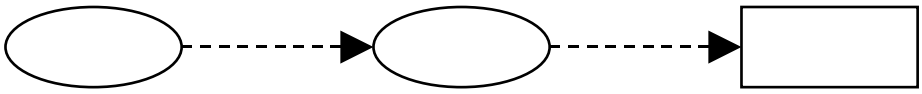
2. Enclose all conditions and causal factors in ovals.



3. Connect primary and secondary events by solid arrows.



4. Connect conditions to other conditions and/or events using arrows with dotted lines.

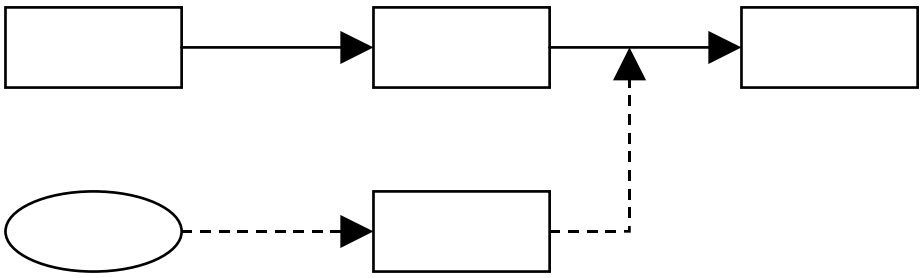


5. Presumptive events, causal factors, or conditions are shown by dotted rectangles or ovals.

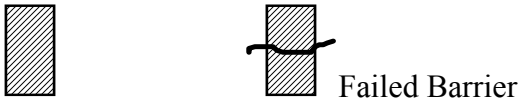
6. The primary sequence of events is depicted in a straight horizontal line with the primary events connected with arrows.

   Relative time sequence is left to right.

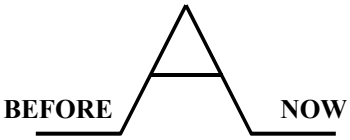
   Secondary event sequences, contributing causal factors, and causal factors are depicted above or below the primary event line.



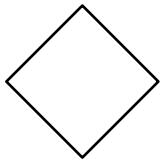
7. Barrier



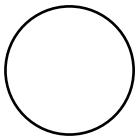
8. Change



9. Inappropriate actions are shown as diamonds

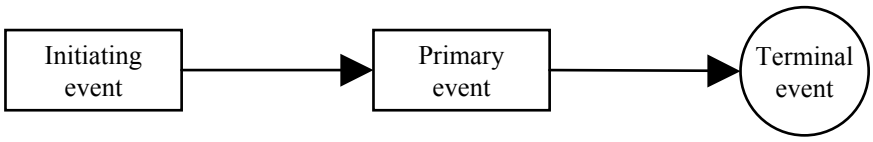


10. Terminal event is shown by a circle

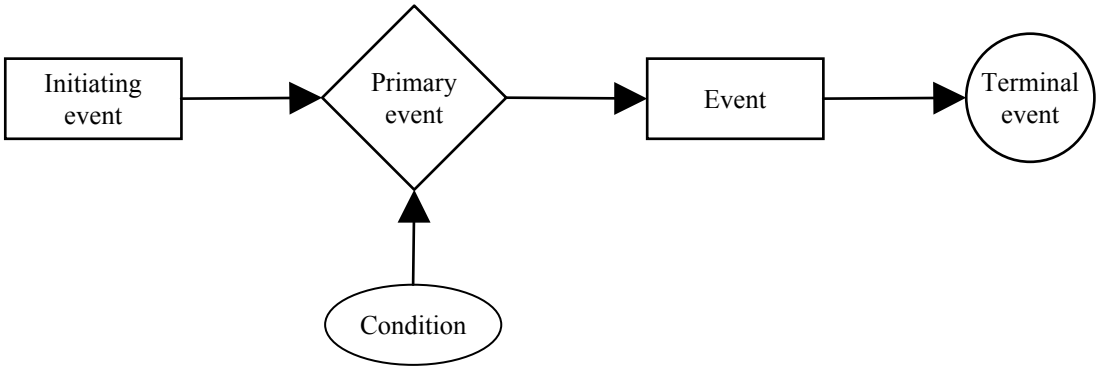


Event & Causal Factor Charting Process

Step 1: Construct preliminary event sequence line with known events. Identify initiating event, terminal event and any known primary effects (things that went wrong and caused the terminal event). Include how and when the event occurred and the consequences.



Step 2: Add secondary events, conditions and presumptive conditions to the preliminary event sequence line. Identify the condition that led up to the primary effect of the inappropriate action.

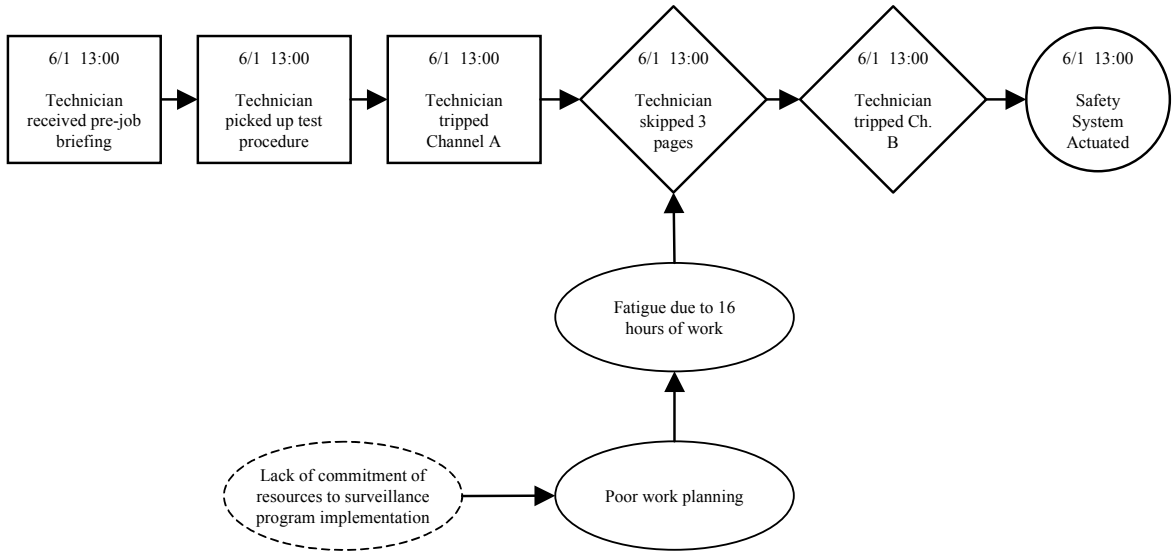


Step 3: Identify gaps and gather new facts from additional investigation.

Step 4: Integrate results from other analysis techniques, e.g., barrier analysis.

Step 5: Add new information to the preliminary chart.

Event And Causal Factor Chart Example



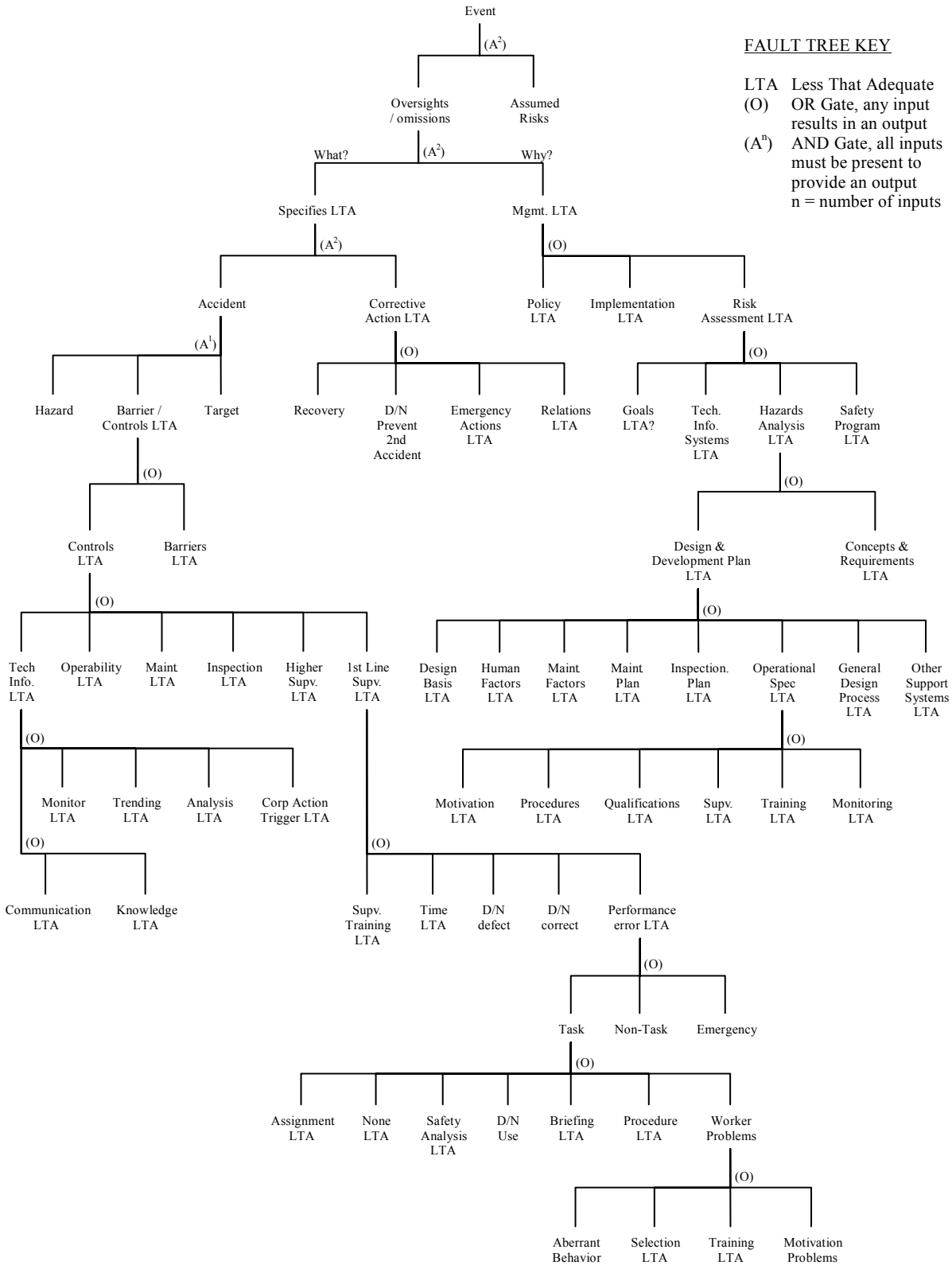
APPENDIX B-4
FAULT TREE ANALYSIS

Fault Tree Analysis

Since the problem(s) associated with the event are known based on the event and causal factor charting, the fault tree analysis flow chart (next page) should be used to identify the programmatic elements that failed during the event.

Starting with event identification at the top of the chart, follow the flow chart to the point at which the problem is known. Based on the various open gates identified using the flow chart, develop a systematic list of questions that will determine why the various gates remained open during the event.

FAULT TREE


Event
(A2)
Oversights / omissions
Assumed Risks
(A2)
What?
Why?
Specifies LTA
Mgmt. LTA
(A2)
(O)
Accident
Corrective Action LTA
Policy LTA
Implementation LTA
Risk Assessment LTA
(A1)
(O)
(O)
Hazard
Barrier / Controls LTA
Target
Recovery
D/N Prevent 2nd Accident
Emergency Actions LTA
Relations LTA
Goals LTA?
Tech. Info. Systems LTA
Hazards Analysis LTA
Safety Program LTA
(O)
(O)
Controls LTA
Barriers LTA
Design & Development Plan LTA
Concepts & Requirements LTA
(O)
(O)
Tech Info. LTA
Operability LTA
Maint LTA
Inspection LTA
Higher Supv. LTA
1st Line Supv. LTA
Design Basis LTA
Human Factors LTA
Maint Factors LTA
Maint Plan LTA
Inspection. Plan LTA
Operational Spec LTA
General Design Process LTA
Other Support Systems LTA
(O)
(O)
Monitor LTA
Trending LTA
Analysis LTA
Corp Action Trigger LTA
Motivation LTA
Procedures LTA
Qualifications LTA
Supv. LTA
Training LTA
Monitoring LTA
(O)
(O)
Communication LTA
Knowledge LTA
Supv. Training LTA
Time LTA
D/N defect
D/N correct
Performance error LTA
(O)
Task
Non-Task
Emergency
(O)
Assignment LTA
None LTA
Safety Analysis LTA
D/N Use
Briefing LTA
Procedure LTA
Worker Problems
(O)
Aberrant Behavior
Selection LTA
Training LTA
Motivation Problems
FAULT TREE KEY
LTA Less That Adequate
(O) OR Gate, any input results in an output
(An) AND Gate, all inputs must be present to provide an output
n = number of inputs

Questions to be asked while performing a "Fault Tree Analysis" should be developed using the "Causal Factor Worksheets," as part of event and causal factor charting. For example, if "Verbal Communications" is identified as a contributing factor to the event, use "Verbal Communications" to develop a list of questions. Examples of questions to be asked include the following:

1. Verbal Communication Problems
   a. Type of Verbal Communications
      - Face-to-face
      - Telephone
      - Intercom/page
      - Hand signal
      - Radio/headset

   b. Communications Contributed to Problem
      - Because pre-job briefing was not performed/completed
      - Because consequences of potential error were not discussed before starting work
      - Because notification was not made/required when job began, was interrupted, or was completed
      - Because shift turnover was not performed/completed
      - Because supervisor was not notified of suspected problem
      - Because pertinent information was not transmitted
      - Because inaccurate message was transmitted
      - Because too much unfamiliar information was presented at once because information communicated was too late
      - Because no means of communication was available
      - Because of inadequate/malfunctioning communication equipment
      - Because of improper use of communication equipment
      - Because change implementation was not properly communicated
      - Because interpretable/non-standard language was used
      - Because receiver was not listening to sender
      - Because much of the information provided exceeded receiver's needs
      - Because priorities of assigned tasks not discussed.

   c. Communications were misunderstood:
      - Because standard terminology was not used
      - Because repeat back was not performed
      - Because message was too long because of a noisy environment
      - Because message was not complete.

   d. No Communication or not timely
      - Because no means or method of communication was available
      - Because events happened too fast
      - Because of time constraints which inhibited taking time to communicate shift or job turnover was incomplete.

APPENDIX B-5
TASK ANALYSIS

Overview

Task analysis is a tool that can be used on virtually any event evaluation; during cause determination it focuses on the task steps and how they are performed. It is reasonable to assume one of the first priorities when beginning an evaluation is to determine as much as possible about the task(s) associated with the event or condition. This should require a review of work documents, logs, technical manuals, and other documents in an effort to determine what the task was about, how it was to be performed, and the desired effect on producing an outcome or equipment used. This process is called a task analysis and may be done in two ways, the paper & pencil task analysis or the walk-through task analysis. Frequently, parts of both will be performed.

Paper and Pencil Task Analysis

Paper and pencil task analysis is a method of task analysis where a task is broken down on paper into sub-tasks identifying the sequence of actions, instructions, conditions, tools and materials associated with performance of a particular task.

Objectives:

- Break down the task into different sub-tasks, actions or steps that are to be performed during the relevant activity.
- Identify information, controls and displays, materials and other requirements for the performance of the task.
- Identify potential questions (concerning deficiencies in procedures, controls/displays and design, training, etc.) to be asked when interviewing the individuals involved.
- Establish a knowledge baseline on how the task being evaluated is to be performed.
- Identify potential problems with the performance of the task such as inadequate procedures, inappropriate plant conditions, and man machine interface issues, etc.

Steps in Paper and Pencil Task Analysis:

1. Obtain preliminary information so you know what the person was doing when the problem or inappropriate action occurred.
2. Decide on task of interest.

3. Get the necessary background information.
   - Relevant procedure(s).
   - System drawings, block diagram, etc.
   - Interview personnel who have performed the task (but not those who will be observed) to gain an understanding of how the task should be performed.

4. Divide the task of interest into component actions or steps.

5. Write step name or action in order of occurrence on the task analysis worksheet.

Paper and Pencil Task Analysis Worksheet:
Paper and pencil task analysis is a method of task analysis where a task is broken down on paper into sub-tasks identifying the sequence of actions, instructions, conditions, tools and materials associated with performance of a particular task.

Objectives:

- Break down the task into different sub-tasks, actions or steps that are to be performed during the relevant activity.

- Identify information, controls and displays, materials and other requirements for the performance of the task.

- Identify potential questions (concerning deficiencies in procedures, controls/displays and design, training, etc.) to be asked when interviewing the individuals involved.

- Establish a knowledge baseline on how the task being evaluated is to be performed.

- Identify potential problems with the performance of the task such as inadequate procedures, inappropriate plant conditions, etc.

Steps in Paper and Pencil Task Analysis:

1. Obtain preliminary information so you know what the person was doing when the problem or inappropriate action occurred.

2. Decide on task of interest.

3. Get the necessary background information.
   - Relevant procedure(s).
   - System drawings, block diagram, etc.
   - Interview personnel who have performed the task (but not those who will be observed) to gain an understanding of how the task should be performed.

4. Divide the task of interest into component actions or steps.

5. Write step name or action in order of occurrence on the task analysis worksheet.

Paper and Pencil Task Analysis Worksheet:

STEPS	WHO	REQUIRED ACTION	COMPONENT	TOOLS	REMARKS/ QUESTIONS

Walk-Through Task Analysis

A walk-through task analysis is a method in which personnel conduct a step-by-step reenactment of their actions for the observer without carrying out the actual function. If appropriate, it may be possible to use the simulator for performing the walk-through rather than the control room.

Objectives

- Determine how a task was really performed.
- Identify problems in human factors design, discrepancies between procedural steps and what is actually done, training, etc.

Preconditions

- Participants should be the people who have previously performed the task successfully.

Steps in Walk-Through Task Analysis

1. Obtain preliminary information so you know what the person was doing when the problem or inappropriate action occurred.

2. Decide on task of interest.

3. Get the necessary background information.
   - Relevant procedure(s).
   - System drawings, block diagram, etc.
   - Interview personnel who have performed the task (but not those who will be observed) to gain an understanding of how the task should be performed.

4. Produce a guide outlining how the task will be carried out, indicating steps in performing the task and key controls and displays so that:

a. You will know what to look for.

b. You will be able to record actions more easily.

- A procedure with key items underlined is the easiest way of doing this.
- The best guide is a completed task analysis worksheet (refer paper and pencil task analysis).

5. Thoroughly familiarize yourself with the guide and decide exactly what information you are going to record and how you will record it. You simply may want to check off each step and controls or displays used as they occur. Discrepancies and problems may be noted in the margin or in a space provided for comments, adjacent to the step.

6. Select personnel who normally perform the task. If the task is performed by a crew, the crew members should play the same role they fulfill when carrying out the task.

7. Observe personnel walking through task and record their actions and use of displays and controls. Note discrepancies and problem areas.

- Walk-through task analysis is normally used to recreate a situation that had human performance problems in a way that provides a sense of how the event occurred.
- Conducting the task under the conditions, as near as possible, that existed when the event occurred will provide the best understanding of the event causal factors.
- Walk-through analysis may be done in slow motion, stopping the task if there are questions.
- Walk-through analysis may be done in real time to better identify time-related problems.

Summarize and consolidate any problem areas noted. Identify probable contributors to the event.

APPENDIX B-6
CORRECTIVE ACTION PLAN DEVELOPMENT

Developing Corrective Actions

a. Corrective actions are developed to address the root, direct and contributing causes, as necessary. Corrective actions developed to address the root cause are known as "corrective action to prevent recurrence" (ATPR). These actions are long term actions designed to preclude recurrence of the adverse or similar condition or event. Remedial actions address the direct and contributing cause(s) and usually restore the plant condition. ALL corrective actions and corrective action plans should include the contribution, collaboration, and agreement of the Issue identifier and the person(s) responsible for the resolving the corrective action.

b. The corrective actions should meet the following (SMART) criteria. They should be:

- Specific - Can you tell who is going to do what when? Are all corrective actions specified in numbers? (Examples: bad - "Clean up the air"; good - "Operations will use high efficiency air filters to reduce particulate contamination to < 0.01 ppm".)

- Measurable - Can the corrective action be measured (quantitatively) to see when it is done and to see if it worked (will it prevent future incidents)? Waiting for an infrequently occurring incident to reoccur is not a good measure of effectiveness. Corrective actions should be developed so when implemented an evaluator can review the expected results to determine the effectiveness of implementation. The corrective action should have a measurable characteristic. For example, a measurable corrective action would contain the following, "Revise step 6.2 of the procedure to reflect the correct equipment location." This measurable attribute would require a review of the procedure to see that the new equipment locations were correct.

- Accountable - Is the person responsible for implementing the corrective action clearly defined? Is the due date clearly specified?

- Reasonable - Will this corrective action work? Is it practical? Can it be implemented? Is there a simpler or less expensive way to do the same thing? Will the corrective action have undesirable effects?

- Timely - Is the due date for the corrective action soon enough given the consequences of another failure? If the frequency of failure is high and the consequences of failure significant, does the report offer interim action to reduce the risk while the final corrective actions are being implemented?

c. Care should be taken when using the terms "review" and "evaluation" in a corrective action statement. There is a variety of formal review and evaluation processes which are conducted

within LANL. Any reference to a specific type of review or evaluation should comply with that procedural process.

d. Corrective actions are assigned a unique action item number using the Institutional tracking system. Sub-activities are also assigned a unique number.

e. Corrective actions should include the following information:

- The corrective action number
- A description of the action
- The responsible action owner
- The action completion due date
- Required completion documentation
- Required closure evidence
- Objective Evidence requirements.

NOTE: Objective evidence requirements are discussed in the next section of this attachment.

f. In developing corrective actions, consideration of the following questions can help lead to effective implementation of actions:

a. Do the corrective actions address the root causes?

b. Will the corrective actions cause detrimental effects?

c. What are the consequences of implementing the corrective actions?

d. What are the consequences of not implementing the corrective actions?

e. What are the capital and O&M costs of implementing the corrective actions?

f. Will training, procedures or other administrative support organization be required as part of the implementation? If so have they been involved with the development?

g. In what time frame can the corrective actions reasonably be implemented?

h. Is management committed to support the resources required for successful implementation of the development of the corrective actions?

i. What resources are required for successful implementation of the corrective actions?

j. What resources are required for successful continued effectiveness of the corrective actions?

k. What impact will the development and implementation of the corrective actions have on other work groups? Such as:

- Plant Engineering
- Quality Control
- Security
- Operations
- Drafting
- Design Engineering
- Document Control
- Training
- Drawing Control
- Plant Modifications
- Materials Management
- Licensing
- Radiological waste
- Work Control Center
- Safety Reviews
- Maintenance
- Health Physics
- Chemistry
- Computer Support
- Configuration Management

l. Will the corrective actions prevent recurrence of the condition and are the results measurable?

m. Is the corrective action within the capability of LANL to implement and within contract provisions?

n. Does the corrective action allow LANL to meet its primary objective of safe and reliable operation of the Tank Farms?

o. Have assumed risks addressed by the corrective action analysis been clearly addressed in the corrective action plan.

Causal Reconciliation

Causal reconciliation is the act of lining-up the problem, causes, and corrective and preventive action. One tool to use for this activity is the development of a causal reconciliation matrix. An example is provided below.

			Corrective and Preventive Actions		
Problem Statement	**Direct and Contributing Causes**	**Root Cause**	**Short Term**	**Longer-Term**	**Actions Complete**
Interlock system failed to shut down equipment in potentially explosive atmosphere	Hydrogen Sensor failure Reconciliation of outstanding design review items LTA Design review process and implementation LTA Integration of risk management inputs LTA Inadequate control of parallel design activities Risk handling activities LTA Reconciliation of design change issues LTA Engineering Task Plan LTA	Management of risk and assurance of rigor is less than adequate for the following areas: • Controlling parallel activities logically done in series • Configuration control especially in compiling design criteria • Definition of roles and responsibilities • New application of existing technology • Design reviews	Design Assumptions: Identify and verify all design selection "enabling" assumptions that are necessary to ensure the success of the interlock system including performance assurance testing. Design Criteria: • Prepare design criteria document • Reconcile al new (evolving design requirements • Reconcile all SAD requirements against these criteria Special expertise: Identify and procure all special expertise Prepare a project-specific design review checklist Develop a compliance matrix to verify all design criteria have been satisfied by design media	Improve engineering test procedure: • Record of decision process • Document design verification methods Design Criteria: • Establish common terminology • Establish and maintain a hierarchy of design criteria documents • Establish a standard for design criteria documents	

APPENDIX B-7

CAUSAL ANALYSIS REPORT TEMPLATE

The purpose of the causal analysis report is to clearly and concisely convey the results of the investigation in a manner that will help the reader *understand what happened* (the issue description and chronology), *why it happened* (the causal factors), and *what can be done to prevent a recurrence* (the judgments of need). Causal results are reported without attributing individual fault or proposing punitive measures.

The causal analysis report constitutes an accurate and objective record of the Issue and provides complete and accurate details and explicit statements of:

- The investigation process
- Facts pertaining to the Issue, including relevant management systems involved
- Analytical methods used and their results
- Conclusions of the causal analysis team, including the causal factors of the Issue
- Judgments of need for corrective actions to prevent recurrence of the accident.

When completed, this report is submitted to the appointing official for acceptance and dissemination.

The causal analysis report is the official record of the causal analysis; its importance cannot be overemphasized. The quality of the analysis will be judged primarily by the report, which will provide the affected organization with the basis for developing the corrective actions necessary to prevent or minimize the severity of a recurrence, as well as lessons learned.

Suggested Report Elements

- The causal analysis report should consist of the elements listed below. They provide a certain level of consistency in content and format among reports which facilitates extraction and dissemination of facts, conclusions, judgments of need, and lessons learned. Elements of the causal analysis report may vary depending on the rigor of analysis.
- Disclaimer
- Appointing Official's Statement of Report Acceptance
- Table of Contents, including list of exhibits, figures, and tables
- Acronyms and Initialisms
- Glossary of Technical Terms (if necessary)
- Prologue—Interpretation of Significance
- Executive Summary
- Introduction—Scope of Investigation, Description of the Accident, Brief Description of Site, Facility, or Area where the Accident Occurred
- Facts and Analysis
- Conclusions and Judgments of Need
- Minority Report (if necessary)
- Board Signatures

- Board Members, Advisors, Consultants, and Staff
- Appendices

Suggested Table of Contents

The table below provides an example table of contents for causal analysis. The elements may vary depending on the rigor of the investigation.

EXAMPLE: TABLE OF CONTENTS

EXHIBITS, FIGURES AND TABLES

APPENDIX B-8
CORRECTIVE ACTION CLOSURE

Objective evidence should be provided for corrective actions (implemented to prevent reoccurrence of the problem or condition). Depending upon the corrective action, specific objective evidence is preferred to support completion of the action. The following provides preferred evidence for specific types of actions.

a. Action Specific Guidance

1) Organizational/Positional Changes

When an action involves an organizational change, it is important to reflect the "before" and the "after" picture.

Example of objective evidence:

- Copies of the "old" and the "new" organization charts with highlighted changes clarify or demonstrate the changed organization components.
- If purpose of re-organization was to accomplish "intent," then there needs to be an explanation as to the value of the new versus the old.

2) Procedure/Command Media Changes

When an action involves a change, modification or deletion of any document associated with LANL command media (e.g. procedures, management directives), care should be taken to assure the objective evidence clearly reflects the changed condition as identified in the corrective action.

Example:

- Proof of procedure changes should include a copy (or changed portion) of the issued procedure.
- Include the redline/strikeout or highlighted/marked version of the procedure showing the changes/revisions. If it is a complete revision, closure statement should be clear.

NOTE: It would be helpful to have an identification of "why" the procedure was changed/what was accomplished? If it is tied into the root cause analysis, then the reason for the change is more obvious.

3) Required Reading

If an action indicates that a required reading activity will be conducted, it is expected that the activity will comply with all applicable LANL procedures associated with the implementation of the formal LANL Required Reading process.

Examples of appropriate closure documentation:

- Company memo that identifies the target group that they have completed the reading.
- Copy of material subject to required reading.
- Copy of required reading completion list.

4) Reviews/Evaluations

Care should be taken when using the terms "review" and "evaluation" in a corrective action statement. There is a variety of formal review and evaluation processes which are conducted within LANL. Any reference to a specific type of review or evaluation should comply with that procedural process.

a. Training

1) Must comply with LANL procedure for training.

2) The ideal closure package associated with a "training" assignment should include the following:

- A list of personnel designated to receive the training and sufficient supplementary material to allow an independent verification that all necessary people were included. Acceptable methods would include use of organization charts, qualification lists, or specific list of personnel, as appropriate
- Copy of Training materials
- Copy of training attendance list. Attendance list needs to correlate with the list of folks who were required to be trained. Would be helpful if we would highlight the folks who were required to be trained on the attendance list.

b. Response that contains "recommendations" and/or "follow-on" actions.

1. If the response contains a recommendation/follow-on action, then documentation that it has been picked-up and tracked would be o.k. There would have to be a decision that these actions are not directly related to the problem we are trying to fix (e.g., not fundamental to the issue).

Corrective action/issue closure and verification
The Issue identifier should be notified when the Issue Owner considers the Issue closed. At this point the Issue identifier should agree that the action is complete and meets the requirements stated in the action plan. This may not be required for all actions, but should be used on High and Medium, significance Issues.

End point assessment or validation
The end point assessment is a method of determining the effectiveness of corrective action implementation. The end point assessment is developed as part of the corrective action plan and presented to Senior Management for review and approval. The end point assessment is a performance-based approach to determine the effectiveness of the corrective action implementation.

The implementation of the corrective actions is measurable. The corrective actions should be developed so when implemented an evaluator can review the expected results to determine the effectiveness of implementation. The responsible manager or assigned evaluator upon reviewing the RCA and the corrective actions should have enough understanding of the problem to determine if it has been resolved, continues to exist and to what extent. For example measurable corrective actions should contain the following, "Revise step 6.2 of the procedure to reflect the correct equipment location," and are these locations being properly reflected in work plans. This evaluation would require the review of the procedure to see that the new equipment locations were correct and if these locations are being properly reflected in work plans used in the field. Corrective action(s) written in the following manner are vague and subjective and are not measurable; "Ensure the actions of procedure step 6.2 are performed correctly in the future."

1. Measurable items to be addressed in the end point assessment may include but are not limited to the following:

   a. Human Performance

      - Verbal communication (Inadequate information exchange face-to-face, telephone)

      - Written procedure and documents (Inappropriate maintenance, operating, or special test procedure/instruction, inappropriate drawing, equipment manual, technical specification)

      - Man-machine interface (insufficient or incorrect label, gauge, annunciator, control device)

- Environmental conditions (inadequate lighting, work space, clothing, noise, high radiation, ambient temperature)
- Work schedule (excessive overtime, insufficient time to prepare for or accomplish the task)
- Work practices (lack of self-check, failure to follow procedure)
- Work organization/planning (insufficient time to prepare or to perform, maintenance not scheduled)
- Supervisory methods (inadequate direction, supervisor interference, overemphasis on schedule)
- Training/qualification (insufficient technical knowledge, lack of training, inadequate training materials, improper use of tools, Insufficient practice, ineffective on-the-job training)
- Change management (inappropriate plant modification; lack of change related retraining, procedures, documents)
- Resource management (unavailability of tools, information, personnel, supervision)
- To ensure previous problem resolved; insufficient use of operating experience; lack of proper assignment of responsibility; not communicating or enforcing high standards; lack of safety awareness).

b. Equipment Performance

- Design configuration and analysis (inappropriate layout of system or subsystem; inappropriate component orientation; component omission; errors in assumptions, methods, or calculations during design or establishing operational limits; improper selection of materials, components; operating environment not considered in original design)
- Equipment specification, manufacture, and construction (improper heat treatment, machining, casting, on-site fabrication, installation)
- Maintenance/testing (inadequate maintenance, insufficient post-maintenance testing, inadequate preventive maintenance, inadequate quality control function)
- Plant/system operation (operating parameters, changes in parameters, performance)

- External (storm, flood, grid perturbation).

* Items in parentheses are provided only as examples of the types of potential causal factors. There may be many similar items in each category.

2. Methods of measuring the effectiveness of corrective action implementation.

   a. An end point assessment does not prescribe the methodology used to perform the assessment. Criteria to determine satisfactory effectiveness of corrective action implementation are provided in the assessment. However, it may provide some suggestions for assessment methodologies to use. Suggestions for evaluation effectiveness of corrective actions that could be addressed in the end point assessment may include but are not limited to the following:

      - A review of the Issues Management database to see if problems addressed in original Institutional tracking system item have occurred since the corrective actions have been implemented.

      - Review of trending data of items or events associated with problem or event (See RCA for predecessors to problem or event).

      - Review similar work activities to see if the resulting actions have resulted in a change in the performance of work.

      - If equipment is involved review equipment history logs to see if any symptom from the first failure are being seen in current operations.

      - Interview individual having responsibility of equipment or utilizing the process to monitor for any improvement.

SUGGESTED END POINT ASSESSMENT REPORT FORMAT

Institutional tracking system Number:

Institutional tracking system Title:

Issue Number:

Performed By: _____ Date: _____
Signature

Reviewed By: _____ Date: _____
Responsible Manager signature

Approved By: _____ Date: _____
LANL Senior Manager signature

END POINT ASSESSMENT REPORT FORMAT (CONT.)

END POINT ASSESSMENT

Institutional tracking system
Number: 4596

Sub Activity Number:	1	SAT / UNSAT
C/A Description:	Establish a common terminology for design requirements	
Actionee:	Frank DeAublow	
Responsible Manager:	Ms. Jane Doe	
Due Date:	05/06/2003	
Closure Evidence:	Completed and approved design requirements terminology dictionary	
Effectiveness Criteria:	Terminology difference in design documents are decreasing	
Comments:		

Sub Activity Number:	2	SAT / UNSAT
C/A Description:	Provide training for cognizant personnel on design requirements terminology dictionary	
Actionee:	Schibunaw Congatwit	
Responsible Manager:	Ms. Jane Doe	
Due Date:	06/03/2003	
Closure Evidence:	Training Lesson Plan, List of qualified engineers	
Effectiveness Criteria:	100% of engineers and 90% of management staff successfully trained.	
Comments:		

Include as attachments any supporting documentation such as copies of logs, interview notes, reports, audit reports, test results, etc.

Page X of XX

SAMPLE ISSUES MANAGEMENT COORDINATOR APPOINTMENT LETTER

To/MS: Addresses, Organization, Mail Stop
From/MS: John Doe, XX-2, KXXX
Phone/Fax: 5-xxx/Fax 5-xxx
Symbol: XX-2:04-0XX
Date: Month XX, 2004

memorandum

AD
Division
Group

Subject: ISSUES MANAGEMENT COORDINATOR APPOINTMENT

By this memorandum I appoint (Jane Doe) as the Issues Management Coordinator for (AD or Division). In this position, Ms. Doe is responsible for implementing the Institutional Issues Management program as described in LIR 307-01-05, *Issues Management Program*, and LIG 307-01-05, *Issues Management Guidance Handbook*.

In this position Ms. Doe has the authority to:
- Screen new issues for significance and reportability,
- Assign issue owners,
- Initiate, investigate, and close issues,
- Enter and modify issue status using the Institutional issues management tracking system, and
- Perform other assigned tasks in implementation of the Issues Management Program.

In addition Ms. Doe will meet with me frequently to discuss the status of issues and associated corrective actions.

Approval Authority Signature: _____ _____
John Doe, XX (AD or Division Leader) Date

XX:xx

Cy: PS-7, K-999
IM-9, A150
XX-2 Files

DOCUMENTING OF CORRECTIVE ACTIONS

Objective evidence of corrective action completion, verification, and validation of corrective action effectiveness should be kept as records per the documentation requirements in Section 6.